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Cognitive rehabilitation for people with mild to moderate dementia (Protocol)

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[Intervention Protocol]

Cognitive rehabilitation for people with mild to moderate dementia

Aleksandra Kudlicka[1], Anthony Martyr[2], Alex Bahar-Fuchs[3], Bob Woods[4], Linda Clare[2]

[1]School of Psychology, University of Exeter, Exeter, UK. [2]REACH: The Centre for Research in Ageing and Cognitive Health, University of Exeter, Exeter, UK. [3]Academic Unit for Psychiatry of Old Age, Department of Psychiatry, University of Melbourne, Melbourne, Australia. [4]Dementia Services Development Centre Wales, Bangor University, Bangor, UK

Contact address: Aleksandra Kudlicka, School of Psychology, University of Exeter, Perry Road, Exeter, Devon, UK. a.kudlicka@exeter.ac.uk.

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

- To evaluate the effects of cognitive rehabilitation on everyday functioning and other outcomes for people with mild to moderate dementia, and on outcomes for caregivers
- To identify and explore factors that may be associated with the efficacy of cognitive rehabilitation

BACKGROUND

Description of the condition

Dementia is a general term for a number of progressive neurodegenerative conditions, arising predominantly in later life. The World Alzheimer Report 2015 estimates that there are 46.8 million people living with dementia worldwide (Prince 2015). The prevalence of dementia doubles every 6.3 years, from 3.9 per 1000 person-years in people 60 to 64 years old, to 104.8 per 1000 person-years for people over 90. Changes in lifestyle and consequently, health status and life expectancy, translate into differences in incidence and prevalence rates between countries and generations. Monitoring the prevalence of dementia is challenging. Data collected in different countries and across various studies cannot be easily compared, due to the diagnostic process, which involves neuropsychological evaluation, interviews, and observation, and is guided by changing diagnostic criteria (Wu 2017). The general trend is for people to live longer, so regardless of these factors, the number of people with dementia is expected to increase to 74.7 million by 2030, and to 131.5 million by 2050. The risk of dementia is higher for those with poorer cardiovascular health, and with worse access to education and healthcare (Prince 2015; Wu 2017).The most common form of dementia is caused by Alzheimer's disease, which accounts for approximately 62% of cases, followed by vascular dementia (17%), and mixed Alzheimer's and vascular dementia (10% (Prince 2014). Rarer forms of dementia include the Parkinsonian dementias (Parkinson's disease dementia, 2%, and dementia with Lewy bodies, 4%), and the behavioural and semantic variants of frontotemporal de-

mentia (2%).

Each type of dementia in the mild to moderate stages has its own profile of cognitive changes, which can be demonstrated on neuropsychological testing, although as dementia progresses further, the differences become less distinguishable. A useful summary is provided by Weintraub 2012. Alzheimer's disease is characterised by impairments in episodic memory; other cognitive domains, such as executive function, are also affected. In vascular dementia, episodic memory may be less impaired, while executive functioning, attention, and perception are more affected. Parkinsonian dementias are characterised by impairment in attention, executive function, and visual perception (Kudlicka 2011). Among the frontotemporal dementias, semantic dementia is characterised by loss of conceptual knowledge and vocabulary; the behavioural variant is characterised by executive dysfunction (Hodges 1992; Snowden 1989).

Cognitive impairments affect functional ability (Martyr 2012a; Royall 2007). Impaired ability to function in daily life is a core feature of dementia, progressing from mild difficulty with instrumental activities of daily living in the early stages, to dependence on others for basic activities of daily living in the later, severe stages (Boyle 2002; Njegovan 2001). Even in the early stages of dementia, impaired functional ability impacts on independence, and may result in loss of confidence, and withdrawal from activities, leading to what has been termed 'excess' or unnecessary additional disability (Reifler 1990). Impairments in functional ability, and associated excess disability, contribute significantly to caregiver burden (Martyr 2014; Razani 2007). Supporting functional ability, by enabling people with dementia to function at their best level, given their underlying impairments, is potentially an important target for intervention (Poulos 2017).

Description of the intervention

Cognitive rehabilitation is a personalised approach, based on a problem-solving framework, which enables people with dementia to engage in, or manage everyday activities, function optimally, and maintain as much of their independence as possible. Rehabilitation denotes a positive approach to enabling people to make the most of their functional ability; in some settings, especially community settings, reablement is a more commonly used descriptor (Poulos 2017). The terms cognitive rehabilitation, and the equivalent, neuropsychological rehabilitation, were first introduced to differentiate this approach from rehabilitation for physical disabilities. Cognitive, or neuropsychological, indicates that the intervention addresses the impact of cognitive impairments on everyday life, and on the engagement in everyday activities. None of these terms imply that the underlying impairment can be removed, or that there are attempts to restore or improve cognitive function; instead, they emphasise a solution-focused approach to manage the everyday challenges that result from the impairment (McLellan 1991).

Originally developed for people living with cognitive impairment as a result of brain injury (Wilson 2002), the cognitive rehabilitation approach was adapted for people with dementia, and is consistent with the values of person-centred dementia care (Clare 2017). Its goal is to support independence and social participation, in line with many European and worldwide organisations that promote strategies to maximise functional ability in the older population, and those with dementia (EIPAHA 2012; Myshra 2016; WHO 2001). It also recognises the right of people with dementia to receive support that enables them to reach their best possible level of functioning. This may be important for the sustainability of healthcare systems, as improved functioning in everyday activities may potentially reduce the need for paid support, unnecessary hospitalisation (Clare 2017), and prevent premature admission to a care home (Amieva 2016). Cognitive rehabilitation practitioners may be drawn from a number of professional backgrounds, such as clinical psychology, occupational therapy or nursing. Often, a qualified practitioner will supervise less qualified staff, such as assistant psychologists or occupational therapy technicians. Other groups of staff, such as home support workers, may be trained to implement this approach under supervision.

The goal of cognitive rehabilitation is to improve functioning in areas that the recipient identifies as relevant and important to them (Clare 2008). These targeted areas are typically outlined in the form of personal goals that the individual wishes to attain. Cognitive rehabilitation for people with dementia is usually conducted in the person's home setting, or the environment in which the targeted activities generally occur. Transfering new learning to different situations is a challenge in behavioural interventions, and this can be avoided by working directly in the context in which the new skills will be used. Consequently, cognitive rehabilitation is usually offered as an individual intervention, rather than in group formats.

If cognitive impairments have progressed to the point where the person does not readily understand or engage in the rehabilitation process, the practitioner may use the cognitive rehabilitation approach to help the caregivers (e.g. family members, care workers, care home staff, or home support staff) develop more effective strategies to support and enable the person with dementia. However, this review will consider interventions for people with mild to moderate dementia, who are still able to engage in the process of identifying their rehabilitation goals.

During the goal-setting process, the cognitive rehabilitation practitioner works with each individual to identify the areas of daily life in which they wish to improve. The practitioner assesses:

1. The person. The practitioner needs to understand the person's current level of functioning, where difficulties arise and why, and whether the person could potentially function better if secondary issues, such as loss of confidence, or lack of necessary support, were to be addressed.
2. The context. The practitioner needs to understand the environment in which the person is operating, and factors that

could either facilitate or hinder progress towards the achievement of their personal goals. This includes the nature of the relationship with family members or friends, and the level of support that might be forthcoming. Family members may have their own priority areas to be addressed, and negotiation may be required to arrive at a set of goals that meets the needs and wishes of both parties.

3. The activity. The practitioner needs to understand the nature and demands of each activity or task that the person wishes to manage better, the steps involved in completing it, and what strategies, if any, have already been tried. If the person is currently doing the activity, the practitioner needs to identify where any problems or difficulties arise, and what needs to change to enable the activity to be undertaken more successfully. Based on this assessment, the practitioner clarifies the goals, ensures they are realistic, and draws on a set of evidence-based or practice-tested methods and techniques to prepare an individual rehabilitation plan. This may include methods to:

- Engender procedural learning through developing habits and routines, for example designate and use a specific place to leave important personal items, learn to make calls and send messages on a smart phone, or use a dosette box to manage medication.
- Reactivate previous knowledge, for example remember and use the names of one's grandchildren.
- Compensate for known difficulties and challenges, for example develop strategies to avoid being distracted and lose concentration when preparing meals, modify tasks or the environment, or introduce assistive technology.
- Build individual strategies to support functioning in specific situations, for example join the conversation at the family dinner table, or re-engage in a previously enjoyed activity.
- Address specific dementia-related difficulties, for example reactivate knowledge of vocabulary and concepts for people with semantic dementia.

Evidence-based techniques used in cognitive rehabilitation interventions include both enhanced learning methods and introduction of compensatory strategies. Enhanced learning methods include modelling; prompting, with gradual fading of prompts; and expanding the rehearsal of information (Clare 2008). While errorless learning approaches are sometimes recommended, evidence suggests that reducing or removing errors during learning does not confer benefits for people with dementia, although making fewer errors may make learning more congenial by reducing the experience of failure (Dunn 2007; Voigt-Radloff 2017). Some activities will be broken down into steps, and practised, one step at a time, until the whole sequence of steps has been mastered. Compensatory strategies and memory aids may be introduced, with the support of the cognitive rehabilitation practitioner, where appropriate.

The cognitive rehabilitation practitioner works with the person, and where appropriate, with his or her family or other supporters, to implement the rehabilitation plan. The practitioner encourages supporters to learn the techniques, so that they can facilitate between-session practice. As people differ in how they respond to particular strategies and techniques, the practitioner may need to try more than one strategy to identify the approach that works best for a given individual. Therefore, the practitioner might adapt the rehabilitation plan, based on ongoing evaluation of its progress, and assessment of the extent to which goals are achieved. Additional elements may be incorporated into the intervention where needed, for example an individual may need to develop anxiety management skills before advancing to selected goals. The level of support may vary in length and number of sessions, and the extent to which the broader personal and social context is addressed, for example it may include help to manage depression and anxiety, or offer support for family members.

In research trials, the cognitive rehabilitation approach may be adapted in order to allow more defined methods of evaluation. For example, a researcher who is not the treating therapist, may set goals and rate progress; this means that therapists may be working with goals to which they had no prior input. Goals may also be selected from a pre-defined list, rather than developing them de novo with the individual. Progress may be evaluated through self- or informant ratings in relation to goals, observation of performance, or objective tests, rather than therapist evaluation of outcomes (Clare 2019a; Voigt-Radloff 2017).

How the intervention might work

Cognitive rehabilitation is a behaviour change intervention, based on an understanding of the cognitive changes seen in mild to moderate dementia, which builds on relatively better preserved cognitive abilities to address and overcome the impact of cognitive impairment. It has long been understood that people with mild to moderate dementia have considerable retained cognitive and behavioural capacities, and are capable of behaviour change and some new learning, given appropriate support (Backman 1992; Fernández-Ballesteros 2003; Little 1986). For example, in Alzheimer's, vascular and mixed dementia memory problems are common. Neuropsychological models distinguish different types and processes of memory, and experimental studies show that these different types of memory are differentially affected; episodic memory (memory for events and personal experiences) is impaired, but procedural memory (learned habits and routines) is relatively spared in people with mild to moderate stages of these types of dementia (Squire 1995). Therefore, by providing strategies that draw on relatively preserved processes, it is possible to compensate for the results of more severe impairment in other areas (Bahar-Fuchs 2013).

Psychologically, the experience of successfully achieving goals and improving everyday function could increase feelings of self-efficacy, and help to counter negative consequences of dementia, such

as loss of confidence, thus reducing excess disability (Marshall 2005).

Family members, or other supporters may benefit in a number of ways. They may feel less burdened as the person with dementia functions better in targeted areas of daily life. They are supported to learn some of the rehabilitative strategies themselves, and can apply them when new difficulties arise after the therapy sessions end. Involvement in the therapy process can improve understanding of dementia and the person's behaviour, which in turn, enables them to have more patience with the person with dementia, and improve the relationship overall (Clare 2019b).

Why it is important to do this review

Impairments in functional ability form part of the diagnostic criteria for dementia, and are a defining characteristic of the condition (APA 2013; WHO 1992). Among people with dementia, better functional ability is associated with higher self- and informant-ratings of quality of life (Bosboom 2012; Dourado 2016; Gómez-Gallego 2012; Heggie 2012; Martyr 2018; Ready 2004; Sheehan 2012; Woods 2014). In mild to moderate dementia, there is a significant decline in ability to carry out instrumental activities of daily living. Diminished functional ability impacts independence, adds to caregiver burden, and can result in a loss of confidence and withdrawal from activities (McLaughlin 2010). Despite this, limited attention has been paid to strategies that support functional ability. Cognitive rehabilitation, if effective, could form a valuable component of support for people with dementia and their families.

In previous Cochrane Reviews, cognitive rehabilitation was included with cognitive training, and the most recent update found only one randomised controlled trial of cognitive rehabilitation (Bahar-Fuchs 2013). For the present review, we separate these two interventions; first, because they are radically different, and second, because the volume of evidence relating to cognitive rehabilitation is gradually increasing.

OBJECTIVES

- To evaluate the effects of cognitive rehabilitation on everyday functioning and other outcomes for people with mild to moderate dementia, and on outcomes for caregivers
- To identify and explore factors that may be associated with the efficacy of cognitive rehabilitation

METHODS

Criteria for considering studies for this review

Types of studies

We will consider randomised controlled trials (RCTs) that compare cognitive rehabilitation with treatment as usual, a waiting-list control, a non-specific active control intervention, or an alternative treatment intervention. We will consider a cross-over design if there are sufficient data available for the first period only (Elbourne 2002). We will exclude other study designs to limit the risk of bias in estimates of treatment effects (Reeves 2011). We will not impose any language or date restrictions in the search strategy. For possibly-relevant studies published in a language other than English, we will attempt to obtain translation. If a translation is not available prior to submission of the completed review, we will file the studies under 'awaiting classification'.

Studies must include, at a minimum, baseline and post-treatment evaluations. Further follow-up, where available, may be of any duration.

Types of participants

Participant characteristics: adults of any age and background. They may, or may not, have an unpaid caregiver (spouse or partner, family member, or friend) who supports their participation, and provides relevant information.

Diagnosis: dementia, of any type, made according to established clinical and research criteria; for example:

- The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V (APA 2013)), or earlier versions (APA 1995)
- The International Classification of Diseases, tenth revision (ICD-10 (WHO 1992))
- The National Institute of Neurological and Communicative Disorders - Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA (McKhann 1984))
- The National Institute of Health - Alzheimer's Association (NIA-AA (McKhann 2011))
- The Association Internationale pour la Recherché et l'Enseignement en Neurosciences (NINDS-AIREN (Román 1993))
- Vascular Impairment of Cognition Classification Consensus Study (McKeith 1996; McKeith 2006; McKeith 2017)
- The International Behavioural Variant FTD Criteria Consortium (FTDC (Skrobot 2018))

Stage of dementia: mild to moderate level of severity, on average, as indicated by group mean scores, score ranges, or individual scores, on measures used to indicate dementia severity. We will use an internationally recognised dementia staging system, the Clinical Dementia Rating (CDR 2), as a reference, along with equivalent scores of another screening tests (Hughes 1982). Mild to moderate level of severity will be indicated by scores of 0.5 to 2

on the CDR; 11 or above on the Mini-Mental State Examination (MMSE (Folstein 1975)); a Montreal Cognitive Assessment raw score of 5 or above (MoCA (Nasreddine 2005; Roalf 2013)), or an Addenbrooke's Cognitive Examination (ACE-III and ACE-R) score of 27 or above (Matías-Guiu 2018; Perneczky 2006). We will not set an upper limit for screening test scores, as the study participants will have to have a diagnosis of dementia. We will include studies where fewer than 20% of participants fall outside of the mild to moderate level of severity, provided this information is clearly indicated.

Pharmacological treatment: participants in both the intervention and control groups may be receiving concurrent pharmacological treatment for dementia as a randomly distributed covariate. Where available, we will note information about participants' use of such medication, including information about whether participants are receiving a stable dose.

Types of interventions

We will include interventions that meet our definition of cognitive rehabilitation. Terminology in the field of non-pharmacological interventions for people with dementia is inconsistent, and researchers may use alternative terms such as reablement or remediation. In some cases, the term cognitive rehabilitation may be incorrectly applied to describe different approaches, such as cognitive training or cognitive stimulation. Cognitive rehabilitation protocols may vary considerably across clinical practice and research trials. For example, cognitive rehabilitation could form part of a comprehensive programme that includes formal therapy for mood disorders and counselling for family members, or the term could refer to a set of techniques that address memory or attention difficulties (Kudlicka 2018). We will define cognitive rehabilitation as a therapy that encompasses interventions that:

- Focus on functioning in everyday activities;
- Address specific targeted activities chosen or identified as important by each individual participant. These activities will usually be expressed in terms of personal goals that the participant wishes to achieve;
- Apply an individual, personalised therapy plan, aimed at improving performance in, or management of, these activities, based on an assessment of the person's current functioning and intrinsic capacity, and on an evaluation of the demands of the targeted activities;
- Use recognised rehabilitative strategies and methods to enable the person to compensate for, manage, or overcome functional limitations, with regard to the targeted activities.

For the purposes of selecting studies for this review, we will operationalise this definition as:

1. It aims to improve functioning in everyday activities (i.e. not on abstract exercises, puzzles, or tests);
2. It is personalised, as indicated by at least one of the following:
   - The therapy objective is chosen by the person with dementia, or a family supporter, or both and may be selected from a list;
   - The therapy plan is based on an assessment of the person's current functioning and capacity; or
   - The therapy strategies reflect the person's ability and therapy objective (i.e. the intervention does not use the same method for every person, every goal, or both)

3. It uses recognised cognitive rehabilitation techniques, including at least one of the following:
   - Graded activity;
   - Modelling;
   - Action-based learning;
   - Expanding rehearsal (also known as spaced retrieval);
   - Prompting and fading;
   - Altering features of the person's environment and surroundings;
   - Mnemonics, elaboration, and vanishing cues for learning or relearning information; or
   - Introducing compensatory strategies such as memory aids.

The practitioner will usually deliver the intervention in the person's home setting, or in the everyday environment in which the targeted activities are undertaken, and provide it on a one-to-one basis, over several sessions. We will consider interventions provided in group formats, if they meet the above criteria. In some cases, cognitive rehabilitation may be combined with other interventions delivered at the same time, such as cognitive training or physical exercise (Bahar-Fuchs 2019). We will exclude trials where this is the case, as it will not be possible to determine the distinct contribution of each intervention element to the outcomes of interest. We will retain studies if the review authors judge that cognitive rehabilitation comprises at least 80% of the actual intervention time.

Comparators

Cognitive rehabilitation may be compared to inactive controls (treatment as usual, a waiting-list control condition), a non-specific active control intervention, or an alternative treatment:

- **Treatment as usual**. This may be described as standard treatment, usual treatment, or no treatment. In this review, usual treatment alone is compared to usual treatment plus cognitive rehabilitation. Usual treatment refers to the treatment usually available in the study locality, and might include memory clinic consultations, provision of medication, contact with a community mental health team, day care, or support from voluntary organisations.
- **Waiting-list control**. Participants allocated to the control group receive no intervention but are informed that they will be offered cognitive rehabilitation once the trial has ended.
- **Non-specific active control**. Participants allocated to the control group engage in a specified activity for an equivalent

number of sessions and have similar levels of contact with the research team, but do not receive a cognitive rehabilitation intervention or other structured intervention.

- **Alternative treatment**. Participants in the comparator group receive another recognised non-pharmacological intervention, which has different components. Non-pharmacological interventions fall into the following three categories that will be used to group alternative treatments: cognition-focused (e.g. reminiscence therapy, cognitive stimulation therapy, brain training), exercise-based (e.g. aerobic training, resistance training), or arts-based (e.g. music therapy, drama therapy).

Use of different comparators is likely to constitute an important source of heterogeneity in the findings.

Types of outcome measures

We will consider behavioural, cognitive, and psychosocial outcomes which are measured at the end of treatment, or at follow-up. Biomarker and economic outcomes are beyond the scope of this review.

Primary outcomes

- Functional ability in targeted activities. The primary outcome of a cognitive rehabilitation intervention is the effect on participants' functional ability to engage in, and carry out the activities specifically targeted in the intervention (Wilson 2002). This may be assessed by means of ratings of performance on a standard scale made by the participant, caregiver, or therapist (or a combination), or through direct observation and recording of performance on specific tasks. An example of a standard scale for rating the attainment of therapy goals is the Canadian Occupational Performance Measure (Law 2005). An example of an observational measure is the Direct Measure of Training (Thivierge 2014).

Secondary outcomes

- General functional ability. A key secondary outcome is the effect on general functional ability, assessed by informant ratings on a standardised scale, such as the Functional Activities Questionnaire (Martyr 2012b; Pfeffer 1982), or a reduction in dependence, assessed by informant ratings on a standardised scale, such as the Dependence Scale (Brickman 2002; Stern 1994).

Other secondary outcomes for the person with dementia are:

- self-efficacy,
- mood,
- quality of life,
- cognition (global and domain-specific), and
- disease severity

Outcomes for caregivers are changes in:

- stress,
- burden,
- coping, and
- quality of life.

We will prioritise published and validated measures, and only accept a non-established measure if we find sufficient evidence to support its statistical properties. In classifying cognitive measures, we will use well-established classifications (e.g. Strauss 2006). Where there are multiple measures for the same outcome, we will follow principles described in Bahar-Fuchs 2019).

Search methods for identification of studies

Electronic searches

We will search ALOIS (www.medicine.ox.ac.uk/alois), the Cochrane Dementia and Cognitive Improvement Group (CDCIG) specialised register. ALOIS is maintained by the Information Specialists for the Cochrane Dementia and Cognitive Improvement Group, and contains studies that fall within the areas of dementia prevention, dementia treatment and management, and cognitive enhancement in healthy older people. The studies are identified through:

1. Searching a number of major healthcare databases: MEDLINE, Embase, CINAHL, and PsycINFO;
2. Searching a number of trial registers: ClinicalTrials.gov and the World Health Organization International Clinical Trials Register Platform (ICTRP), which covers ISRCTN; the Chinese Clinical Trials Register; the German Clinical Trials Register; the Iranian Registry of Clinical Trials; and the Netherlands National Trials Register;
3. Searching the Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
4. Searching grey literature sources: ISI Web of Science Core Collection.

To view a list of all sources searched for ALOIS, please visit the ALOIS website: www.medicine.ox.ac.uk/alois.

Details of the search strategies run in healthcare bibliographic database and used for the retrieval of reports of dementia, cognitive improvement, and cognitive enhancement trials can be viewed on the Cochrane Dementia and Cognitive Improvement Group website: http://dementia.cochrane.org/searches.

We will run additional searches in MEDLINE, Embase, PsycINFO, CINAHL, LILACs, ClinicalTrials.gov, and the WHO Portal/ICTRP to ensure that the searches for this review are as comprehensive and current as possible. See Appendix 1 for the search strategy we will use to retrieve reports of trials from MEDLINE Ovid (Appendix 1).

Searching other resources

We will screen reference lists of included trials, and of relevant systematic reviews and practice guidelines identified during the screening process.

Data collection and analysis

Selection of studies

We will prepare a complete list of search results, with duplicate records removed. We will test the eligibility criteria on a selection of 10 to 12 studies, and will refine and clarify the criteria to maximise consistency of the screening process. Two review authors, working independently, will screen titles and abstracts, and exclude articles that both review authors agree are ineligible. We will discuss any disagreements on eligibility, and if we cannot reach consensus, will refer the abstract in question to a third review author. Where there is any doubt, we will retain the abstract. We will retrieve the full-text articles for all abstracts retained at this stage, and two review authors, working independently, will review them. We will discuss any disagreements on eligibility, and if we cannot reach consensus, will refer the article in question to a third review author. We will group multiple reports from the same trial under a single study identifier. We will contact study authors for further details if we require clarification. To prevent any conflicts of interest arising, review team members who have authored reports of studies being considered for inclusion at any stage of the selection process will not be involved in decisions about the inclusion of those studies; instead, we will refer the studies to other review team members for a decision.

Data extraction and management

We will prepare and use a structured proforma for data extraction, from which we will transfer and manage data in Review Manager 5.

From each trial, we will extract data, including detailed characteristics of the trial, its setting, design and outcomes; participant characteristics (diagnosis, age, gender, education, dementia severity and medication use); and the experimental and comparator interventions (nature, intensity, frequency, and duration). For each outcome of interest, we will extract means and standard deviations of relevant measures from all available evaluations. Where available, we will also extract information about potential effect moderators: adherence and retention, intervention integrity and fidelity, and adverse events.

Assessment of risk of bias in included studies

Two review authors, working independently, will use the Cochrane 'Risk of bias' tool to assess bias in the domains of sequence generation, allocation concealment, blinding of participants and investigators, incomplete outcome data, and selective reporting of outcomes (Higgins 2017). We will refer disagreements that we cannot resolve through discussion to a third review author. We will rate studies as low risk, high risk or unclear risk in each of these domains. Review team members will not rate any studies for which they are co-authors; these studies will be referred to other team members for rating.

Measures of treatment effect

For continuous outcomes, we will use the mean difference (MD) with 95% confidence interval (CI) when studies used the same rating scale to measure a particular outcome, and the standardised mean difference (SMD), which is the absolute mean difference divided by the pooled standard deviation, when the same outcome is assessed by different rating scales. We will calculate effect estimates, with 95% CIs, using change-from-baseline scores. Baseline is defined as the latest available assessment prior to randomisation, undertaken not more than two months beforehand. Where change scores are not reported, we will extract the mean, standard deviation, and number of participants at each assessment point, for each group, and calculate the change scores. We will base calculations of the standard deviation of change scores on an assumption that the correlation between measurements at baseline and those at subsequent time points is zero. This method overestimates the standard deviation of the change from baseline, but it is considered preferable in a meta-analysis to take a conservative approach.

For dichotomous outcomes (e.g. institutionalisation), we will express effects as risk ratios (RR), along with 95% CIs.

We will decide whether to treat ordinal outcome data as continuous, or to dichotomise, following data extraction, depending on the number of categories. We will treat outcome measures with more than 10 categories as continuous variables arising from a normal distribution (Bahar-Fuchs 2019).

Unit of analysis issues

Cross-over trials

We will use data from the first treatment period, prior to cross-over, only.

Trials with multiple comparator conditions

We will conduct separate analyses for each type of comparator, where sufficient data are available. Alternative treatments serving as comparators will be grouped by category (e.g. cognition-focused, exercise-based, arts-based) to facilitate comparison across studies.

Duration of follow-up

As follow-up durations will vary, we will group these for purposes of analysis in bands of time since the end of treatment assessment to facilitate comparisons (i.e. 3 to 6 months, 7 to 12 months, 13 to 18 months, 19 to 24 months, and > 24 months). Where a given study has more than one assessment point within a time band, we will use data from the latest assessment. We will note any contact with the research team during the follow-up period (for example, for maintenance or 'booster' sessions).

Dealing with missing data

We will identify the number of participants included in the final analysis as a proportion of all participants recruited and randomised.

Assessment of heterogeneity

In addition to visual inspection of forest plots, we will assess statistical heterogeneity using a standard Chi^2 statistic and the associated I^2 statistic (Higgins 2003). We will consider heterogeneity to be substantial when the Chi^2 statistic is significant at the P = 0.1 level, or when the I^2 suggests that more than 40% of the variability in effect estimate is due to heterogeneity (Deeks 2017).

Assessment of reporting biases

For the primary outcomes, we will evaluate the presence of reporting bias through a visual examination of funnel plots if 10 or more studies are included in a meta-analysis (Egger 1997).

Data synthesis

We will conduct data synthesis in Review Manager 5.
For each outcome of interest, where available data permit, we will undertake the following separate comparisons:

- Cognitive rehabilitation versus control (inactive and non-specific active controls) at the end of therapy.
- Cognitive rehabilitation versus control (inactive and non-specific active controls) at subsequent follow-up.
- Cognitive rehabilitation versus alternative treatment at the end of therapy.
- Cognitive rehabilitation versus alternative treatment at subsequent follow-up.

For alternative treatment comparators, we will conduct separate analyses for the following categories of comparator: cognition-focused, exercise-based, and arts-based interventions.
For multiple follow-ups, we will group comparable time points, and conduct separate analyses for each time point.
Within each of the planned comparisons, we will pool data in relation to each outcome of interest when data from at least two trials are available. We will conduct inverse-variance, random-effects meta-analyses for all outcomes.

GRADE and 'Summary of findings' tables

We will apply the GRADE framework to all primary and secondary outcomes in each comparison, classifying the certainty of evidence as high, moderate, low or very low. We will include this classification in the 'Summary of findings' (SoF) tables. For each comparison, we will use GRADEpro GDT software to generate 'SoF' tables for the following primary and secondary outcomes:

- Functional ability in targeted activities
- General functional ability
- Self-efficacy
- Mood
- Quality of life
- Cognition (global)
- Quality of life (caregivers)

Subgroup analysis and investigation of heterogeneity

In relation to each outcome, we will carry out sub-group analyses if there is evidence of substantial heterogeneity, and there are at least three studies per subgroup. These analyses will evaluate the potential impact of the following factors that might modify observed treatment effects:

- Intervention intensity (number of sessions and duration of intervention period)
- Type of dementia
- Type of practitioner (practitioner profession and qualification level)
- Risk of bias (studies with high or unclear risk of bias in two or more domains versus studies with less risk of bias)
- Registration status of the trial (registered versus not registered)
- Type of control condition (inactive versus non-specific active control)

Sensitivity analysis

Where indicated by the data we will use sensitivity analyses to clarify uncertainties relating to eligibility criteria, data, and analysis methods in the identified studies, following Cochrane guidelines. For example, in the presence of substantial heterogeneity, we will explore the effect of small studies by comparing fixed-effect and random-effects estimates; we will use a 'trim and fill' technique to address publication bias.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy for MEDLINE Ovid

1 exp Dementia/
2 exp DELIRIUM/
3 exp Neurocognitive Disorders/
4 exp Aphasia, Primary Progressive/
5 exp Wernicke Encephalopathy/
6 PDD.ti,ab.
7 korsako*.ti,ab.
8 huntington*.ti,ab.
9 dement*.ti,ab.
10 deliri*.ti,ab.
11 binswanger*.ti,ab.
12 alzheimer*.ti,ab.
13 (pick* adj2 disease).ti,ab.
14 (lewy* adj2 bod*).ti,ab.
15 (creutzfeldt or jcd or cjd).ti,ab.
16 (chronic adj2 cerebrovascular).ti,ab.
17 (cerebral* adj2 insufficient*).ti,ab.
18 (cerebr* adj2 deteriorat*).ti,ab.
19 ("normal pressure hydrocephalus" and "shunt*").ti,ab.
20 "primary progressive aphasia".ti,ab.
21 "Parkinson* disease dementia".ti,ab.
22 "organic brain syndrome".ti,ab.
23 "organic brain disease".ti,ab.
24 "major neurocognitive disorder*".ti,ab.
25 "benign senescent forgetfulness".ti,ab.
26 or/1-25
27 exp Cognitive Remediation/
28 exp Cognitive Remediation/
29 exp Cognitive Therapy/
30 exp Rehabilitation Nursing/
31 "activities of daily living".ti,ab.
32 "Cog* retrain*".ti,ab.
33 "cognitive intervention*".ti,ab.
34 ("Cognitive skills" adj2 training).ti,ab.
35 "cognitive support".ti,ab.
36 "memory aid*".ti,ab.
37 "memory function*".ti,ab.

38 “memory group*”.ti,ab.
39 “memory management”.ti,ab.
40 “Memory rehabilitation”.ti,ab.
41 “memory retraining”.ti,ab.
42 “memory re-training”.ti,ab.
43 “memory stimulation”.ti,ab.
44 “memory strateg*”.ti,ab.
45 “memory support”.ti,ab.
46 “memory training”.ti,ab.
47 “restorative care”.ti,ab.
48 (cognit* adj2 rehabilitation).ti,ab.
49 (cognit* adj2 retrain*).ti,ab.
50 (cognit* adj2 stimulation).ti,ab.
51 (cognit* adj2 training).ti,ab.
52 (memory adj2 rehabilitation).ti,ab.
53 (memory adj2 therap*).ti,ab.
54 “restorative care”.ti,ab.
55 reablement.ti,ab.
56 (rehabilitation/ or rehab*.ti,ab.) and (activities of daily living/ or Attention/ or executive function/ or attention.ti,ab. or planning.ti,ab. or “activities of daily living”.ti,ab. or “executive function”.ti,ab.)
57 or/27-56
58 26 and 57
59 randomized controlled trial.pt.
60 controlled clinical trial.pt.
61 randomized.ab.
62 placebo.ab.
63 drug therapy.fs.
64 randomly.ab.
65 trial.ab.
66 groups.ab.
67 or/59-66
68 exp animals/ not humans.sh.
69 67 not 68
70 58 and 69

CONTRIBUTIONS OF AUTHORS

Linda Clare drafted the protocol on behalf of Aleksandra Kudlicka, who was on maternity leave. All co-authors reviewed the draft and contributed to revising it.

DECLARATIONS OF INTEREST

Aleksandra Kudlicka - author of a potentially eligible study

Anthony Martyr - author of a potentially eligible study

Alex Bahar-Fuchs - none known

Bob Woods - author of a potentially eligible study

Linda Clare - author of a potentially eligible study

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Internal sources

- No sources of support supplied

External sources

- NIHR, UK.

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